

K010987

JUN 19 2001

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

Applicant: Karl Storz Endoscopy - America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 558-1500

Contact: James A. Lee
Regulatory Affairs Specialist

Device Identification: Common Name:
Miniature Telescope and Accessories

Trade Name: (optional)
KSEA MINIATURE TELESCOPE AND ACCESSORIES

Indication: The KSEA Miniature Telescope and Accessories used by qualified surgeons to visualize the surgical site during diagnostic and therapeutic endoscopic arthroscopy in the small joints, including the jaw, toes, elbow, wrist, ankle, hand and fingers, and in diagnostic procedures in large joints such as the knee.

Device Description: The KSEA Miniature Telescope is a fiber optic micro-endoscope for arthroscopy. The body contact portions of the KSEA Miniature Telescope and Accessory are composed of chromium plated Monel 400® and surgical grade stainless steel, which are commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

Substantial Equivalence: The KSEA Miniature Telescope and Accessories are substantially equivalent to the predicate devices since the basic features, dimensions, materials and intended uses are identical or similar. The minor differences between the subject and the predicate devices raise no new issues of safety and effectiveness, as these differences have no effect on the performance, function or intended use of these devices.

Signed: James A. Lee

James A. Lee
Regulatory Affairs Specialist



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2001

Mr. James A. Lee
Regulatory Affairs Specialist
Karl Storz Endoscopy-America, Inc.
600 Corporate Pointe
Culver City, California 90230

Re: K010987

Trade/Device Name: KSEA Miniature Telescope and Accessories
Regulation Number: 888.1100
Regulatory Class: II
Product Code: HRX
Dated: March 30, 2001
Received: April 2, 2001

Dear Mr. Lee:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. James A. Lee

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

K010987

510(k) Number (if known):

Device Name: KSEA Miniature Telescope and Accessories.

Indications for Use: To visualize the surgical site during diagnostic and therapeutic endoscopic arthroscopy in the small joints, including the jaw, toes, elbow, wrist, ankle, hand and fingers, and in diagnostic procedures in large joints such as the knee.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dmitriy Chee MD for CDRH
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010987

✓
Prescription Use: _____ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)